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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC., Plaintiffs, v. ANCHEN PHARMACEUTICALS, INC. Defendant.	Civ. No. 11-cv-06348-JAP-(DEA) (Consolidated for discovery purposes with Civ. No. 11-cv-02317-JAP-DEA and Civ. No. 11-cv-04275-JAP-DEA)

ANCHEN'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Defendant Anchen Pharmaceuticals, Inc. ("Anchen") submits this response to the Opening *Markman* Submission of Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively, "Plaintiffs") for the disputed claim terms of U.S. Patent No. 6,926,907 ("the '907 patent"), U.S. Patent No. 6,369,085 ("the '085 patent"), U.S. Patent No. 7,411,070 ("the '070 patent"), and U.S. Patent No. 7,745,466 ("the '466 patent") (collectively, "the Patents-in-Suit."). Each of Plaintiffs' proposed constructions is inconsistent with the meaning of the claim terms in light of its specification and prosecution history, and cannot be reconciled with the relevant extrinsic evidence regarding the use of those terms in the art. In addition, Plaintiffs' constructions impermissibly add vagueness to the claims. In contrast, Anchen's constructions provide clear and definite meaning to the claim terms at issue, while also being true to both the intrinsic and extrinsic evidence. Anchen's constructions, therefore, should be adopted.

In cases Civ. No. 11-cv-02317-JAP-DEA and Civ. No. 11-cv-04275-JAP-DEA, now consolidated with the present case for discovery (the "Consolidated Cases"), Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (together "DRL"), and Lupin Ltd. and Lupin Pharmaceuticals Inc. (together "Lupin") are jointly filing a brief titled "DRL and Lupin's Responsive Claim Construction Brief" (the "DRL/Lupin Response") concurrently with Anchen's filing of this response. As specifically indicated *infra*, Anchen adopts stated portions of the DRL/Lupin Response addressing certain claim terms in the patents listed above.[1] This response generally focuses on disputed claim terms not addressed in the DRL/Lupin Response.

[1] The DRL/Lupin Response has been designated as "Highly Confidential" under the Stipulated Discovery Protective Order (D.I. 42) in this matter and filed under seal. To the extent certain

II. SUMMARY OF ANCHEN'S RESPONSE

With regard to the '907 patent, Plaintiffs' constructions are in stark contrast with what the patentee consistently and unequivocally held out as being its invention. For instance, Plaintiffs acknowledge that, in the asserted invention of the '907 patent, "[t]he delayed release coating would prevent release of the NSAID in the stomach *until* the amount of acid there had been reduced to safe levels…." Plaintiffs' Opening *Markman* Submission ("Pl. Op. Br."), D.I. 101, at 2 (emphasis added). This fundamental aspect of the asserted invention is captured in Anchen's construction of the phrase "wherein said unit dosage form provides for coordinated release." Anchen's Opening Claim Construction Brief ("Anchen Op. Br."), D.I. 100, at 4.[2] Yet Plaintiffs attempt to distance themselves from the patentee's purported invention. Specifically, Plaintiffs ignore that the claims require the gastric pH to rise to above 3.5 "upon administration… of one or more" tablets including an acid inhibitor, and that this rise in gastric pH results in "coordinated release" of the NSAID. Because Anchen's construction preserves an essential aspect of the alleged invention, it should be adopted.[3]

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sections of the DRL/Lupin Response are incorporated into this document, Anchen designates those incorporated sections (and those sections only) as Highly Confidential, and their incorporation in this document shall not serve to circumvent any order to seal any portion of the DRL/Lupin Response.

[2] Anchen construes this phrase to mean "release of the NSAID in the unit dosage form is prevented until the acid inhibitor in the unit dosage form increases gastric pH [to at least 3.5]."

[3] Plaintiffs' construction, in essence, is significantly broader than the invention disclosed in the '907 patent, which requires the acid inhibitor to raise the pH of the stomach as a precondition to release of the NSAID in the stomach. Because Plaintiffs' construction omits an element the patentees deemed essential to their invention, it is improper. *See Gentry Gallery, Inc. v. Berkline Corp.,* 134 F.3d 1473, 1479 (Fed. Cir. 1998) ("[I]t is clear that [the inventor] considered the location of the recliner controls on the console to be an essential element of his invention. Accordingly, his original disclosure serves to limit the permissible breadth of his later-drafted claims."). For the same reason, Plaintiffs' construction would render the claims invalid. Anchen intends to amend its invalidity contentions accordingly if Plaintiffs' construction is adopted.

Plaintiffs' construction of the term "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon administration of one or more of said unit dosage forms" is similarly irreconcilable with fundamental aspects of the alleged invention as described by the patentee. The '907 specification clearly shows the invention involved the use of acid inhibitors present in an amount effective to raise gastric pH to at least 3.5 "upon administration of one or more of said unit dosage forms," and that the "one or more of said unit dosage forms" is meant to cover the situation in which a patient takes more than one tablet or capsule at once. Plaintiffs' construction should therefore be rejected. Anchen's construction, however, preserves this meaning—the "acid inhibitor is present in the unit dosage form in an amount effective to raise gastric pH to at least 3.5 *at the time the unit dosage form is administered*"—and should therefore be adopted.

With regard to the '085, '070 and '466 patents (the "trihydrate patents"), Plaintiffs' construction of the term "characterized by the following major peaks in its X-ray diffractogram" increases the ambiguity of the claim language, rather than reducing it, and outright ignores certain limitations of the claims. Further, Plaintiffs' construction of this term lacks any basis in the intrinsic or extrinsic record. Anchen's construction, however, provides meaning for the claim term and simplifies any determinations with regard to noninfringement and invalidity. Likewise, Plaintiffs' construction of the term "represented by FIG. 1," while facially based in the claim language, provides no further guidance as to the scope of the claim or how to determine noninfringement or invalidity of the claim. Because Anchen's proposed constructions are better grounded in the language of the claim, while also providing a basis on which to assess invalidity and noninfringement, the Court should adopt Anchen's constructions.

III. U.S. PATENT NO. 6,926,907

Anchen adopts the section of the DRL/Lupin Response addressing the '907 patent with the following additional claim terms and arguments.

A. "wherein said unit dosage form provides for coordinated release"

Claim(s)	Plaintiffs' Construction	Anchen's Construction
5, 15, 52-54	wherein the single entity for drug administration provides for the sequential release of acid inhibitor followed by NSAID	release of the NSAID in the unit dosage form is prevented until the acid inhibitor in the unit dosage form increases gastric pH [to at least 3.5][4]

Anchen's construction of this phrase requires that the release of the NSAID in the unit dosage form is prevented until the acid inhibitor in that same unit dosage form has raised gastric pH (*i.e.*, the amount of acid in the stomach has been reduced to safe levels). Plaintiffs acknowledge the importance of this concept to the asserted invention of the '907 patent. Pl. Op. Br. at 2. Yet their proposed construction ignores it.

Plaintiffs seek to close debate on the meaning of "coordinated release" by citing a single passage from the '907 patent that allegedly equates "coordinated release" with "sequential release," and arguing that "[t]he use of '*i.e.*' in this passage indicates the patentee's intent to define 'coordinated release' to mean 'the sequential release of acid inhibitor followed by [NSAID].'" Pl. Op. Br. at 9 (citing *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009)). But Plaintiffs fail to mention that the '907 patent also uses "*i.e.*" in another passage describing "coordinated release," namely:

> A unit dosage form of the present invention preferably provides for coordinated drug release, in a way that elevates gastric pH and reduces the deleterious effects of the NSAID on the gastroduodenal mucosa,

[4] The "to at least 3.5" language in Anchen's construction is included simply to provide context for the language found earlier in the claim, i.e. "an acid inhibitor present in an amount effective to raise the gastric pH of said patient *to at least 3.5*" (emphasis added). The "to at least 3.5" language is not itself in dispute and does not itself form a part of Anchen's proposed construction for the phrase "wherein said unit dosage form provides for coordinated release."

> *i.e.*, the acid inhibitor is released first and the release of NSAID is delayed until after the pH in the GI tract has risen.

'907 patent at 3:62–4:2 (emphasis added). This passage requires coordinated release "in a way that elevates gastric pH" by releasing the acid inhibitor first and delaying release of the NSAID until after the pH has risen. *See also* Response dated July 22, 2004 at 3 ("the dosage form deliver[s] these drugs in a coordinated fashion *such that the acid inhibitor is released first and the NSAID is not released until after the gastric pH of the patient is 3.5 or higher*" (emphasis added)).[5]

Plaintiffs' construction thus takes a single passage in the specification and uses it to define the invention, rather than construing the claims in light of the entirety of the intrinsic evidence. This renders Plaintiffs' construction improper. *See Digital Biometrics, Inc. v. Identix, Inc.,* 149 F.3d 1335, 1345 (Fed. Cir. 1998) ("[Plaintiff] points to one isolated passage in the written description to support its claim construction ... This isolated passage therefore does not alter our construction, which is based on the entire written description."). Anchen's construction, in contrast, captures the mechanism by which the disclosed dosage form achieves "coordinated release" because it states that "release of the NSAID in the unit dosage form is prevented until the acid inhibitor in the unit dosage form increases the gastric

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[5] Indeed, Plaintiffs' own expert, Dr. Robert Williams admits that it is necessary to delay the release of the NSAID until after the pH has risen.

> Q. In the context of the '907 patent, do you believe it's necessary for the NSAID to be delayed until after the pH in the GI tract has risen?
> A. Well, I mean, the claim term that I construed is the NSAID is – basically, the release of the NSAID is prevented unless the pH of the surrounding medium is 3.5 or higher. So that's what the claim term says.

Deposition of Dr. Robert O. Williams, III ("Williams Dep."), Ex. 1 to Declaration of Crystal R. Canterbury ("Canterbury Decl.") in support of Anchen's Responsive Claim Construction Brief, 111:15-21, Sept. 19, 2012. All Exhibits are attached to the Canterbury Declaration accompanying this brief.

pH [to at least 3.5]." Because Anchen's construction is supported by the totality of the intrinsic evidence considered together, and not merely by a single isolated passage devoid of context, it should be adopted.

Further, the Examples in the '907 patent refute, rather than reinforce, Plaintiffs' construction. While Plaintiffs point to the Examples in the '907 patent as supporting their proposed construction, Pl. Op. Br. at 10 (citing '907 patent at 8:35-49; 9:50-62), these Examples are each directed to tablets containing famotidine as the acid inhibitor and methacrylic acid copolymers as the delayed release coating. *See* '907 patent at 8:14-15, 40-41; 9:39-40, 52-56. Famotidine is a fast-acting acid inhibitor that raises gastric pH within 40 minutes after administration. *See* D. Decktor *et al.*, "The Action of 10 mg Famotidine Versus 200 mg Cimetidine: Onset and Magnitude of Antisecretory Action Within the First 2 Hours After Administration," AM. J. OF THERAPEUTICS 5, 97–100 (1998), Ex. 2 to Canterbury Decl., at 100. And Plaintiffs admit that "[t]he function of methacrylic acid copolymers is to prevent the release of naproxen until the pH of the stomach rises." '907 patent at 10:60-62. This exemplary dosage form would work exactly as the patentee contemplated: release of the NSAID (naproxen) does not occur until the acid inhibitor (famotidine) raises gastric pH. Thus, the Examples cited by Plaintiff support Anchen's construction of "wherein said unit dosage form provides for coordinated release" to mean "release of the NSAID in the unit dosage form is prevented until the acid inhibitor in the unit dosage form increases gastric pH."[6]

[6] Plaintiffs erroneously allege that "Anchen seeks to limit the release of the NSAID to only one part of the GI tract – the stomach…." Pl. Op. Br. at 10. Consistent with Anchen's construction of claim term 3, however, release of the NSAID may depend on time or pH, and the location of NSAID release in the GI tract has no bearing on Anchen's construction of the "coordinated release" term.

Plaintiffs bow to reality when they admit, as they must, that their proposed construction of the "coordinated release" term would result in the '907 patent covering "a dosage form that passes through an 'unprotected stomach,'" *i.e.*, where the acid inhibitor in the dosage form *has not had any effect* on gastric pH, and releases the NSAID in the small intestine. Pl. Op. Br. at 11. This example shows how Plaintiffs' overly broad construction cannot be correct. Since the acid inhibitor in this example has not had any effect on gastric pH, the dosage form would operate no differently than an enteric coated NSAID, which the patentee criticizes. *See* '907 patent at 1:57-63. Because Plaintiffs' proposed construction ignores the patentee's statements on scope of coverage, it should be rejected. Anchen's construction is consistent with the patentee's statements and so should be adopted.

B. "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon administration of one or more of said unit dosage forms"

Claim(s)	Plaintiffs' Construction	Anchen's Construction
5, 15, 52-54	an acid inhibitor present in an amount capable of raising the gastric pH of said patient to at least 3.5 upon the administration of one or more single entities for drug administration over a period of time.	an acid inhibitor is present in the unit dosage form in an amount effective to raise gastric pH to at least 3.5 at the time the unit dosage form is administered

Anchen's construction of this term should be adopted because it imparts greater clarity to the claim. Plaintiffs' construction not only ignores the words "upon administration" but also allows for the self-contradictory administration of "one… single entity… over time." Anchen's construction, in contrast, requires that the acid inhibitor in the unit dosage form be present in an amount effective to raise gastric pH to at least 3.5 at the time the unit dosage form is administered.

Contrary to Plaintiffs' allegation, Anchen's construction does not limit the claims by reading out the "or more" language. *See* Pl. Op. Br. at 6. Simply put, it is irrelevant to the construction whether one or more unit dosage form is administered because it is necessary for the acid inhibitor present in any single unit dosage form to be present in an amount effective to raise gastric pH to at least 3.5 at the time the unit dosage form is administered. Anchen's construction embraces both the "one" and the "or more" possibilities. Plaintiffs' assertion to the contrary is incorrect.

In contrast to Anchen's construction, which contemplates administration of one or more unit dosage forms to raise gastric pH to at least 3.5, Plaintiffs' construction effectively eliminates the possibility of one single unit dosage form working to raise gastric pH to at least 3.5. Indeed, the Plaintiffs' construction embraces the possibility that the "acid inhibitor is present in an amount capable of raising the gastric pH of said patient to at least 3.5 upon the administration of one … single [entity] for drug administration over time," without stating how it is possible to administer one single entity for drug administration "over a period of time."

Further, Plaintiffs' expert, Dr. David Johnson, testified that administration of a single unit dosage form would not work despite the clear language of claim 1 requiring "an acid inhibitor present in an amount effective to raise gastric pH of said patient to at least 3.5 upon the administration of *one* … of said unit dosage forms."

> Q. That's not my question. I'm asking, can you give an expert opinion as to whether the administration of one single unit dosage form can raise the gastric pH of a patient to 3.5 or higher?
>
> A. Again, it would not be predictable, and it would not be standard, and it would not be mechanistically how these drugs would work.

Deposition of Dr. David A. Johnson, M.D. ("Johnson Dep."), Ex. 3 to Canterbury Declaration, 122:16-22, Sept. 11, 2012.

Dr. Johnson's conclusion that one single unit dosage form would not work is based on the flawed premise that "at least 3.5" requires a steady-state pH that is reached after several days, weeks, months, or years of administration. Johnson Dep., Ex. 3 to Canterbury Declaration 106:10 – 107:13. Dr. Johnson's opinions, however, do not comport with what the applicant claimed as its invention, which is merely reaching a gastric pH of at least 3.5.

Plaintiffs' construction improperly requires repeated administration of the single unit dosage form over a period of time. As support, Plaintiffs rely on the declaration of their expert, Dr. Johnson, who contends that a person of ordinary skill in the art "would understand 'an amount effective' in the claim language at issue to include amounts of PPIs that are effective upon administration one or more times over a period of time." Declaration of Dr. David A. Johnson, M.D. ("Johnson Decl."), Ex. 4 to Canterbury Declaration, at ¶ 37.

Dr. Johnson's contention suffers from several infirmities. First, it disregards the '907 patent's express claim language, which a person of ordinary skill in the art would understand to require "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 ***upon the administration*** of one or more of said unit dosage forms." Rebuttal Declaration of Dr. Roy Orlando, M.D. ("Orlando Rebuttal Decl."), Ex. 5 to Canterbury Declaration, at ¶ 4 (emphasis added); '907 patent, claim 1 (emphasis added). In other words, the claim requires that the acid inhibitor raise gastric pH at the time the unit dosage form is administered. *Id*. Thus, the fact that this may be difficult or even impossible is simply irrelevant.

Second, Dr. Johnson's opinion also fails because it is factually incorrect. For example, it is inconsistent with the '907 patent's own specification. Specifically, the '907 patent contemplates dosages of PPIs in the range of 5 mg to 600 mg per unit dose and, as such,

describes a dose range that would enable even a single dose of PPI to raise gastric pH to 3.5 or above. Orlando Rebuttal Decl., Ex. 5 to Canterbury Declaration, at ¶ 5. Therefore, Plaintiffs' construction that "an 'amount effective' would include amounts of acid inhibitors that are effective upon administration of one or more times over a period of time" is belied by the intrinsic evidence.

Plaintiffs also allege that Anchen's construction excludes the preferred embodiment from the claims. This is incorrect. The '907 patent does not list proton pump inhibitors such as esomeprazole as preferred embodiments; instead, the specification lists the preferred acid inhibitors as H2 receptor antagonists generally and famotidine specifically. '907 patent at 3:28-36. These acid inhibitors, as well as other acid inhibitors present in an amount effective to raise gastric pH to at least 3.5 at the time the unit dosage form is administered, are within Anchen's construction.

Plaintiffs argue that PPIs such as omeprazole, which require repeated administrations over several days to become effective, would be excluded from the claims under Anchen's construction. *See* Pl. Op. Br. at 7-8. Such drugs are not the preferred embodiments however, but merely "[o]ther agents that may be effectively used." '907 patent at 3:36-38.[7] Thus, the case law cited by Plaintiffs is inapposite. *See Sinorgchem Co. v. Int'l Trade Comm'n*, 511 F.3d 1132, 1138 (Fed. Cir. 2007) ("Where, as here, multiple embodiments are disclosed, we have previously interpreted claims to exclude embodiments where those embodiments are inconsistent with unambiguous language in the patent's specification or prosecution history."). It is clear from the

[7] Plaintiffs cite the '907 patent at 7:9-11 as support for their assertion that PPIs such as omeprazole are preferred acid inhibitors. *See* Pl. Op. Br. at 8. This passage, however, merely indicates that "[f]or example, the proton pump inhibitor omeprazole should be present in tablets or capsules in an amount from 5 to 50 mg, with about 20 mg per unit dosage form being preferred" ('907 patent at 7:9-11), and does not indicate any preference for PPIs generally or omeprazole specifically as the acid inhibitor.

'907 specification that the applicant made a conscious and deliberate decision to direct its claims to acid inhibitors present in an amount effective to raise gastric pH to at least 3.5 *at the time the unit dosage form is administered*. Plaintiffs' effort to retroactively annul this decision should be rejected.

C. "a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher"

Claim(s)	Plaintiffs' Construction	Defendants' Construction
5, 15, 52-54	No construction is needed. This phrase should be given its plain and ordinary meaning.	a coating that, upon ingestion of said unit dosage form by said patient, controls the release of NSAID by time or pH and thereby prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher

Anchen adopts the section of the DRL/Lupin Response addressing the construction of this claim term.

D. "at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5" and "enteric coating"

Claim(s)	Plaintiffs' Construction	Defendants' Construction
5, 15, 52-54	at least a portion of said proton pump inhibitor is immediately released	at least some amount of acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5
5, 15, 52-54	"enteric coating" means a delayed release coating	"enteric coating" means a coating that controls the release of an active agent from a unit dosage form by pH

Anchen adopts the section of the DRL/Lupin Response addressing the construction of these claim terms.

IV. U.S. PATENT NOS. 6,369,085, 7,411,070, AND 7,745,466

A. "magnesium salt of S-omeprazole trihydrate"

Claim(s)	Plaintiffs' Construction	Defendants' Construction
'466 patent; claims 1-5, 7-14, and 16. '070 patent; claims 1-4. '085 patent; claims 1-4 and 12.	"magnesium salt of" means a compound formed between positively-charged Magnesium (Mg) cations and negatively-charged S-omeprazole anions. "S-omeprazole trihydrate" means (S)-omeprazole having a structure that has a theoretical ratio of three molecules of bound water per molecule of ((S)-omeprazole)2 magnesium, but which does not necessarily contain exactly three molecules of water, whose structure may be determined by analytical methods identified in the patent and known to those of ordinary skill. In the '085 patent the structure is determined by examining XRD.	a trihydrate of a magnesium salt of S-omeprazole containing three molecules of water per molecule of magnesium salt of S-omeprazole in a unit cell of the crystal lattice that is substantially free from magnesium salts of R-omeprazole and other prior art forms of magnesium salts of S-omeprazole including S-omeprazole dihydrate and amorphous forms

Anchen adopts the section of the DRL/Lupin Response addressing the construction of this claim term.

B. "highly crystalline form"

Claim(s)	Plaintiffs' Construction	Defendants' Construction
'466 patent; claims 4, 12 '085 patent; claims 2-4, and 12.	a form having a repeating pattern of atoms or molecules in an order that can be detected by techniques known in the art, that is more ordered than previously known and disclosed forms.	having a crystallinity higher than any other form of magnesium salt of S-omeprazole disclosed in the prior art

Anchen adopts the section of the DRL/Lupin Response addressing the construction of this claim term.

C. "characterized by the following major peaks in its X-ray diffractogram"

Claim(s)	Plaintiffs' Construction	Anchen's Construction
'085 patent; 1–4, 12 '466 patent; claims 3, 11	identifiable by reference to an X-ray diffractogram that includes the major peaks below	having all of the referenced major peaks in its X-ray diffractogram

Anchen's construction requires that the X-ray diffractogram of a compound according to claim 1 of the '085 patent and claims 3 and 11 of the '466 patent have all of the referenced major peaks recited in Table 1. This construction imparts needed clarity to claim 1 of the '085 patent and claims 3 and 11 of the '466 patent. In particular, Anchen's construction clarifies that any compound with an X-ray diffractogram lacking any recited peaks is not an infringing compound. This is consistent with the language of the claim, which states that S-omeprazole magnesium trihydrate is "characterized by the following major peaks," and then recites a table including the location and relative intensity of each peak in the diffractogram.

Plaintiffs' construction, in contrast, ignores the claim language. Plaintiffs contend their construction means that "while the S-omeprazole trihydrate at issue should be 'identifiable by reference' to a diffractogram including the listed peaks, it does not necessarily have to exhibit all the listed peaks." Pl. Op. Br. at 28. Plaintiffs' construction would thus read *explicit limitations* out of the claim. This fact alone renders Plaintiffs' construction incorrect. *See Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.,* 93 F.3d 1572, 1583 (Fed. Cir. 1996) (finding that the patentee need not have included a particular limitation in its claim, but that "having done so, it must live with the language it chose.").

Further, Plaintiffs' construction introduces greater ambiguity into the claim language. It would make it unclear whether a sample of S-omeprazole trihydrate having a diffractogram that contains some, but not all, of the peaks listed in the table would infringe claim 1 of the '085

patent. Plaintiffs' construction, as such, ignores that the patentee drafted these claims to recite that the compound is "characterized by *the following* major peaks in its diffractogram," rather than "characterized by *at least some of the following* major peaks in its diffractogram." If the diffractogram contains some of the peaks, but at very different intensities from those recited in the table, does that compound infringe? If the diffractogram contains only the peaks listed as having "very strong" (vs) and "strong" (s) intensities, does the compound infringe? Plaintiffs' construction raises rather than resolves such questions.

Plaintiffs also misconstrue the intrinsic evidence in support of their construction. For example, Plaintiffs state that "the intensities provided in Table 1 and the claims at issue are 'less reliable' than other characterization metrics" and cite to column 5, lines 25-30 of the '085 patent in support of this assertion. However, that portion of the specification states that the "relative intensities" extracted from FIG. 1 "are less reliable, and instead of numerical values the following definitions are used," followed by definitions of how the percent relative intensity corresponds to vs (very strong), s (strong), m (medium), w (weak) and vw (very weak). *See* the '085 patent, 5:25-42. In essence, the patentee defined certain relative measures for peak intensity, and required the peaks in the diffractogram to match those relative measures rather than the absolute quantitative measure of peak intensity. The '085/'466 patent specification thus does not state anything about the reliability of "other characterization metrics" relative to XRPD.

Likewise, while the specification does indicate, in the cited section, that certain "very weak peaks have been omitted" from Table 1, the specification provides no guidance as to why such peaks were eliminated, nor that the peaks included in Table 1 may be ignored when characterizing a compound. That certain peaks were "very weak" and were not included in the list of peaks recited in the specification and claims does not serve to diminish the importance of the

other peaks that were included, nor does it indicate that certain peaks may be read out of the claims. Further, the claim language identifies the peaks in Table 1 as "major peaks," presumably in distinction from other "minor peaks," which would include the "very weak" peaks that were not included in Table 1. As such, the patentee defined each peak in Table 1 as a "major peaks," excluded those peaks that were not "major peaks," and thus defined the invention as including compounds with an X-ray diffractogram containing *each major peak listed in Table 1*. As such, Plaintiffs' proposed construction of this term lacks support in the intrinsic evidence.

As a final note, none of the extrinsic evidence cited by Plaintiffs specifically supports their construction over Anchen's construction. Plaintiffs argue that "characterize" means "a distinguishing feature or quality" and that Patent and Trademark Office practice regards such a term as inclusive or open-ended and not excluding additional, unrecited elements. Anchen's construction, however, is in line with these definitions as well, and in fact is more consistent with these definitions than Plaintiffs' construction. For instance, a peak cannot be considered a "distinguishing feature or quality" of esomeprazole magnesium trihydrate if its presence or absence in an X-ray diffractogram could equally indicate the presence of esomeprazole magnesium trihydrate or any other form of esomeprazole magnesium.

Clearly, the claim language requires that the X-ray diffractogram of the claimed product must include all of the peaks listed. Plaintiffs' proposed construction fails to capture this essential concept, and so must be rejected. Anchen's construction, in contrast, clarifies that only a compound "having all of the referenced major peaks in its X-ray diffractogram" is covered by the claim. As such, Anchen's construction should be adopted.

D. "represented by FIG. 1"

Claim(s)	Plaintiffs' Construction	Anchen's Construction
'070 patent; claims 2, 4 '466 patent; claims 2, 10	represented by Figure 1 of the '070 patent (or '466 patent)	having an X-ray powder diffractogram the same as FIG. 1

Claim 2 of the '070 patent and claims 2 and 10 of the '466 patent recite that the claimed magnesium salt of S-omeprazole trihydrate "is represented by FIG. 1." Anchen's construction imparts meaning to this claim term that is consistent with its usage. In particular, Anchen's construction highlights that, for these claims to read on a compound, the compound must have an X-ray diffractogram identical to that in FIG. 1. Anchen's construction thus meaningfully incorporates FIG. 1 into the limitations of the claim.

Plaintiffs allege that this claim language should be given its plain meaning. Allegedly to elucidate that meaning, however, they argue that the specification "makes it clear that 'represented by' does not have to mean 'the same as.'" Pl. Op. Br. at 29. Plaintiffs' construction thus introduces greater uncertainty into the meaning of the claim term. Indeed, Plaintiffs fail to identify what, if any, differences could be present in an X-ray diffractogram such that it would be "represented by FIG. 1" but not the same as FIG. 1. Would a compound having a diffractogram with additional peaks infringe this claim? Would a compound having a diffractogram missing certain peaks infringe this claim? Would a compound having a diffractogram with different peak intensities infringe this claim? Plaintiffs' construction has no power to resolve these issues, while Anchen's construction provides a conclusive basis for answering such questions.

Further, while the Plaintiffs say their interpretation of the term "represented by" is supported by the intrinsic evidence, they merely point to a statement that a compound's X-ray diffractogram "complies" with that in FIG. 1. *Id.* (citing the '070 patent, 9:49-50). The fact that

the diffractogram of that compound "complies" (whatever that may mean) with FIG. 1 does not evince whether that diffractogram was the same as, or differed from, the one depicted in FIG. 1. Nor does that statement suggest *which* differences, exactly, may exist between a diffractogram of a compound according to claim 2 of the '070 patent (or claims 2 and 10 of the '466 patent) and that depicted in FIG. 1.

Anchen's construction, therefore, provides needed specificity to the claim, while Plaintiffs' construction vitiates it. In the context of the '070 and '466 patents, "represented by" *must* mean that the claimed product has an X-ray diffractogram that is *the same* as the X-ray diffractogram of Figure 1—neither reference to any portion of the specification or file history permits a different conclusion. Anchen's construction must therefore be adopted.

V. CONCLUSION

For the foregoing reasons, Anchen respectfully requests that this Court adopt the constructions of the disputed terms that have been proposed by Anchen.

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Respectfully submitted,

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